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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/489,394	01/21/00	HSEI	F1085R6

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EXAMINER
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ART UNIT	PAPER NUMBER
1642	

DATE MAILED:

05/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/489,394

Applicant(s)

Hsel et al

Examiner

Larry R. Helms Ph.D.

Group Art Unit

1642

☒ Responsive to communication(s) filed on 26 Feb 2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-7, 9-11, 13, 15, 16, 18-24, and 26-37 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-7, 9-11, 13, 15, 16, 18-24, and 26-37 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☒ The proposed drawing correction, filed on 26 Feb 2001 is ☒ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. Claims 1-7, 9-11, 13, 15-16, 18-24, 26-37 are pending.
Claims 1, 9, and 15 have been amended.
Claims 1-7, 9-11, 13, 15-16, 18-24, 26-37 are under examination.
2. The text of those sections of title 35, USC Code not included on the Office Action can be found in a prior Office Action.
3. The following Office Action contains some NEW GROUNDS of rejection

Drawings

4. The drawing corrections are acknowledged.

Information Disclosure Statement

5. The information Disclosure statement filed 2/26/01 has been noted, however, none of the references were provided. The patents cited as references 1-31 have been considered. All other references will be considered when the references are provided.

Rejections Withdrawn

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6. The rejection of claims 1-30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims and arguments.

7. The rejection of claims 1-37 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 8, 10, 15, 18, 19, 21, 24, 25, and 30-35 of copending Application No. 09/234182 is withdrawn in view of the terminal disclaimer filed 2/26/01.

8. The rejection of claims 1-37 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 and 28-31 of copending Application No. 09/355014 is withdrawn in view of the terminal disclaimer filed 2/26/01.

9. The rejection of claims 1-13, 15-16, 18-24, 26-33, 36-37 under 35 U.S.C. 103(a) as being unpatentable over Faanes et al (U.S. Patent 5,695,760, filed 4/24/95) is withdrawn in view of the amendments to the claims.

10. The rejection of claims 1-13, 15-33, 36-37 under 35 U.S.C. 103(a) as being unpatentable over Faanes et al (U.S. Patent 5,695,760, filed 4/24/95) and further in view of Zapata et al (FASEB J. 9:A1476, 1995) is withdrawn in view of the amendments to the claims.

11. The rejection of claims 1 and 34-35 under 35 U.S.C. 103(a) as being unpatentable over Faanes et al (U.S. Patent 5,695,760, filed 4/24/95) and further in view of Harlow et al (Antibodies A Laboratory Manual, Cold Spring Harbor Laboratories, pp 324-339, 1988) is withdrawn in view of the amendments to the claims.

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Response to Arguments

12. The rejection of claims 1-7, 9-11, 13, 15-16, 18-24, 26-37 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained and made again.

Claim 1 has been amended to recite limitations of canceled claim 14 which was originally rejected in this rejection in the previous Office Action.

The response filed 2/26/01 has been carefully considered but is deemed not to be persuasive. The response cites references of McCafferty et al (Nature 348:552-554, 1990) and Hollinger et al (PNAS 90:6444-6448, 1993) to provide evidence that a disulfide bond between the light chain and the heavy chain is not needed for antigen binding. In response to these arguments, the cited references are not commensurate in scope with the claims. While it is known in the art that scFv and diabodies do not contain a disulfide bond covalently associating the light and heavy chains, the claims recite antibody fragments that do not contain a disulfide bond but contain a non-proteinaceous polymer linked to a cysteine residue in the light or heavy chain. The claims are not drawn to a scFv or diabodies as required in the claims. The importance of the interchain disulfide bond is underscored by Haber (Biochemistry 52:1099-1106, 1964) which states that the two peptide chains are held together by a single disulfide bridge and incorrect position of the interchain bridge may result in an inactive conformation (see page 1105). In addition, Tout et al also states the importance of the interchain disulfide bond to lead

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to functional assembly of the antibody as removal of the Cys128 did not lead to functional assembly of the L chain and stable association between the H and L chains (see page 153, left column). As stated in the previous Office Action, the specification fails to teach an example where the disulfide bond linking the cysteine residues in the light or heavy chain is substituted for an amino acid and the cysteine is covalently coupled to a nonproteinaceous polymer that results in a functional antibody.

Thus, undue experimentation would be required to make and use the instantly claimed antibody fragments.

The following is a NEW GROUND of rejection.

13. Claims 1-7, 9-11, 13, 15-16, 18-24, 26-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-7, 9-11, 13, 15-16, 18-24, 26-37 are indefinite for reciting “portion of a parental antibody” in claim 1 because the exact meaning of the phrase is not clear. Does the phrase mean a heavy and light chain and an amino acid residue, or a light and heavy chain and a Fc region, etc?

Conclusions

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14. No Claims are allowed. U.S. Patent 6,133,426 is not being used as prior art because the disclosure of antibodies and conjugates of non-proteinaceous polymer wherein the cysteine residue in the light or heavy chain is conjugated to a polymer is not enabled (the claims in 6,133,426 are not directed to this subject matter).

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with

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alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879


SHEELA HUFF
PRIMARY EXAMINER